JUL 18 2012

zimmer spine

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

SUBMITTER:	Zimmer Spine, Inc.
ESTABLISHMENT REGISTRATION NUMBER:	1649384
CONTACT PERSON:	David Padgett, RAC (US) Project Manager Regulatory Affairs Telephone: (512) 533-1998 Fax: (512) 219-5463
DATE:	10 July 2012
TRADE NAME:	PathFinder NXT ® Minimally Invasive Pedicle Screw System
COMMON NAME:	Pedicle Screw Spinal System
Classification Name and Reference:	Pedicle Screw Spinal System 21 CFR § 888.3070, NKB

DEVICE DESCRIPTION:

The existing, commercially available Zimmer Spine PathFinder NXT® system consists of various screws, rods and associated accessories and is intended to provide temporary stabilization following surgery to fuse the spine. PathFinder NXT screws are polyaxial cannulated designs with a range of spinal rod lengths. PathFinder NXT allows the surgeon to place polyaxial pedicle screws either through an open or mini-open procedure. PathFinder NXT is designed to aid in the surgical correction of several types of spinal conditions and intended only to provide stabilization during the development of a solid fusion with a bone graft. These implants are intended to be removed after the development of a solid fusion mass. Additionally, the PathFinder NXT MIS System includes instrumentation to facilitate the implantation of the PathFinder NXT implants. The prior 510(k) for the PathFinder NXT MIS System included both Class I 510(k) exempt instrumentation and those instruments considered to be accessories to the implant. PathFinder NXT was cleared via 510(k) #K100845 on 21 September 2010.

The Fixed Percutaneous Rod Holder accessory that is the subject of this premarket notification instrument is intended for use with the PathFinder NXT® Pedicle Screw System. This instrument is designed

specifically for use with the rod implant component of the PathFinder NXT® Pedicle Screw System and, is considered an accessory to the implant. The Fixed Percutaneous Rod Holder holds and inserts a rod percutaneously through the extender sleeves which are positioned on the implanted screw head.

INDICATIONS for Use:

When intended for pedicle screw fixation from T1 –S1, the indications include immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, deformities or curvatures (i.e. scoliosis, kyphosis, and/or lordosis), tumor and failed previous fusion.

As pedicle screw system placed between L3 and S1, the indications include Grade 3 or Grade 4 spondylolisthesis, when utilizing autologous bone graft, when affixed to the posterior lumbosacral spine, and intended to be removed after the solid fusion is established.

Predicate Device:

Zimmer Spine, Inc. PathFinder NXT® Minimally Invasive Pedicle Screw System, #K100845

Device Technological Characteristics and Comparison to Predicate Device(s):

Zimmer Spine Inc. has submitted documentation demonstrating the substantial equivalence of the modified PathFinder NXT instrument to the original version of the device.

The unmodified and modified versions of the Zimmer Spine PathFinder NXT® System differ only in the design of the Fixed Percutaneous Rod Holder accessory. The unmodified versions of the instrument and the proposed version have the same intended use, operate on the same technological principles, are both manufactured from the same material (–17-4PH Stainless Steel), are cleaned and sterilized in the same way with the same parameters, and have similar designs. In addition, the steel utilized for the proposed and unmodified instrument meet the ASTM A-564 "Standard Specification for Hot-Rolled and Cold-Finished Age-Hardening Stainless Steel Bars and Shapes".

PERFORMANCE DATA:

Design Verification Testing conducted, (1) reliability testing under anticipated clinical loads, and (2) aggressive use simulations to test the fatigue strength when subjected to excessive loading beyond foreseeable misuse to determine survivability and extent of impact on intended use (function), demonstrated that the proposed device is substantially equivalent to the predicate device.

Substantial Equivalence:

Zimmer Spine Inc. has submitted documentation demonstrating the substantial equivalence of the modified and unmodified versions of the PathFinder NXT® System. The proposed Fixed Percutaneous Rod Holder instrument is similar to the predicate version of the instrument in general form, materials, sterilization and cleaning, and intended use. As demonstrated by supporting tests and descriptions, this design modification does not present new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Zimmer Spine, Incorporated
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Project Manager, Regulatory Affairs
5301 Riata Park Court, Building F
Austin, Texas 78727

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Re: K121671
Trade/Device Name: Pathfinder NXT ® Minimally Invasive Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNH, MNI
Dated: June 05, 2012
Received: June 06, 2012

Dear Mr. Padgett:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin Keith

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K121671

Device Name: **PathFinder NXT ® Minimally Invasive Pedicle Screw System**

Indications for Use:

When intended for pedicle screw fixation from T1 –S1, the indications include immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, deformities or curvatures (i.e. scoliosis, kyphosis, and/or lordosis), tumor and failed previous fusion.

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Prescription Use _X_ AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K121671